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Attorney Docket No. T2328-906561

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES**

Appellant: Colin Anthony Kemp :
Serial No.: 09/601,106 :
Filed: September 15, 2000 : Examiner: Frank Choi
For: METHOD AND COMPOSITION FOR TREATING : Art Unit: 1616
ERECTILE DYSFUNCTION EMPLOYING
GLYCERIL TRINITRATE AND LANOLIN : Confirmation No. 5597

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following Brief on Appeal is submitted in support of the appeal of the Office
Action mailed January 28, 2004, wherein the Examiner finally rejected claims 24-29.

The appeal fee of \$165.00 is submitted herewith.

Please charge any additional fees due (or credit any overpayment thereof) to Deposit
Account No. 50-1165 (Docket No. T2328-906561).

Respectfully submitted,
MILES & STOCKBRIDGE

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June 28, 2004
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REAL PARTY IN INTEREST

The real party in interest herein is Futura Medical Developments Limited, to which the above-captioned application is assigned by virtue of an Assignment from the inventor executed November 27, 2002, which was recorded June 16, 2003, on Reel 014173 at Frame 0947.

RELATED APPEALS AND INTERFERENCES

The invention herein is related to no existing patent appeals or interferences.

STATUS OF CLAIMS

The above-captioned application was filed with original claims 1-12. Claims 1-12 as well as claims 13-23, which were added during prosecution of the application, have been cancelled. This is an appeal from the final rejection of claims 24-29, all of the claims remaining in the application.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final Office Action, mailed January 28, 2004.

SUMMARY OF THE INVENTION

This invention relates to a preparation for topical application to the male sexual organ for the treatment of erectile dysfunction.

The present invention is predicated on the discovery that nitroglycerin (glyceryl trinitrate) can be used as a vasodilator in a composition for topical application to the penis in conjunction with carrier materials without also employing either a vasoconstrictor or

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dimethyl sulfoxide, the latter being known to be a toxic material, and that such compositions are effective for the treatment of erectile dysfunction.

One embodiment of the invention provides a combination of compounds in a composition for the treatment of erectile dysfunction in human males, the compounds comprising glyceryl trinitrate and lanolin.

According to another aspect of the invention, a method of treatment of erectile dysfunction in males comprises applying to the penis a composition comprising an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin of the penile shaft. The glyceryl trinitrate acts as a vasodilator in the invention according to its established utility for example in the treatment of angina pectoris. However, in simple combination thereof with lanolin there is also provided an effective treatment of erectile dysfunction in human males. The lanolin acts as a lubricant or moisturizer and also enhances skin absorption of the glyceryl trinitrate.

Optionally, compositions according to the invention may also include a physical stabilizer such as a paraffin cream and other ingredients such as fragrances and/or colorants. The compositions may also include water to adjust the overall viscosity or consistency and concentration of the active ingredient to the desired levels.

ISSUES ON APPEAL

Claims 24-29 stand finally rejected under 35 USC 112, second paragraph, for several informalities. An Amendment is submitted herewith that corrects these informalities, thereby rendering the rejections under 35 USC 112 moot.

Claims 24-28 stand finally rejected under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC §103 as obvious over JP 61286327 (Abstract) (hereinafter, "JP").

Claims 24-29 stand finally rejected under 35 USC 103 as being unpatentable over JP in view of Heaton et al.

An issue presented for appeal is whether JP completely anticipates each and every element of claims 24-28.

A second issue presented for appeal is whether the Examiner has made out a *prima facie* case of obviousness, within the meaning of 35 USC §103 based on the teachings of JP, of the invention defined by claims 24-28.

A third issue presented for appeal is whether the Examiner has made out a *prima facie* case of obviousness, within the meaning of 35 USC §103 based on the combined teachings of JP and Heaton, of the invention defined by claims 24-29.

A fourth issue presented for appeal is whether, assuming that *prima facie* cases of obviousness have been made out by the Examiner, appellant has satisfactorily rebutted the same by a valid showing of unexpected or unobvious results associated with the invention.

GROUPING OF CLAIMS

Appellant will concede that all of the appealed claims stand or fall together.

ARGUMENTS

Claims 24-28 stand finally rejected under 35 USC 102(b) as anticipated by JP. The Examiner states:

“---JP 61286327 expressly discloses an ointment containing nitroglycerin 10, lactose 90, 25% H2O-containing lanolin 600 and white Vaseline® to 1000 g falling within the scope of applicant's claims---”

The question arises, however, to what do the numerals, “10”, “90” and “600” after, “nitroglycerin”, lactose” and “lanolin”, respectively refer. Since the Abstract utilizes percentages, i.e., “25%”, and amounts, i.e., “1000 g”, to define the quantities of two of the ingredients disclosed, i.e., amount of H₂O in the lanolin and amount of vaseline®, respectively, in the composition, it is impossible to ascertain the exact nature of the composition disclosed. The Examiner states:

“---it is clear from the reference that the ointment contains 10 grams of nitroglycerine, 90 grams of lactose, 600 grams lanolin of which 25% is water, and Vaseline up to 1000 grams.---”

It is respectfully submitted however, that this assumption by the Examiner requires a reading into the disclosure of JP limitations that are not present therein nor reasonably discernible therefrom. There is no basis in the reference itself, given the above-noted confusing and inconsistent use of values for the various numerical recitations therein, for the values arbitrarily assigned by the Examiner.

Accordingly, reversal of this ground of rejection is respectfully requested.

Claims 24-28 stand finally rejected under 35 USC 103 as obvious over JP. The Examiner states:

“---A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus, despite the fact the claims recite an effective amount to treat erectile dysfunction, the limitation defines some amount and the prior art discloses an amount. The burden is on Applicant to show that that amount disclosed in the prior art does not fall within the scope of the limitations---” (emphasis added).

As noted above, however, the reference does not disclose the amounts of the various ingredients in terms that would enable one skilled in the art to ascertain the “amounts” referred to by the Examiner for the purposes of shouldering the burden imposed. How does

appellant know what “amounts” of the ingredients disclosed by JP to utilize in any comparison.

Since the reference itself is fatally confusing and vague, it is submitted that the Examiner has not made out a *prima facie* case of obviousness and, therefore, a reversal of this ground of rejection is respectfully requested.

Claims 24-29 stand finally rejected under 35 USC 103 as unpatentable over JP in view of Heaton. The deficiencies of JP as a proper primary reference are noted above. With respect to Heaton, the Examiner states:

“---Heaton et al. teach that nitroglycerin applied topically is effective in dilating arterial blood vessels and treating impotence---”.

The Examiner acknowledges that the prior art does not disclose the amounts of ingredients specified in the claims, but argues that these amounts are readily ascertainable by those skilled in the art. However, given the inherent confusion inherent in the JP disclosure with respect to amounts of ingredients present in the composition, it would be impossible for that skilled artisan to know where to begin to “readily ascertain” the operable amounts.

The Examiner’s reasoning fails to take into account, however, that it is based upon a hindsight reconstruction of the invention utilizing the applicants’ disclosure as a template for selecting isolated disclosures from two separate references containing disparate and unrelated teachings and combining them to arrive at the claimed invention in the absence of any suggestion in the references themselves that they can be so combined. In order to justify a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. Ex parte Walker, 135 USPQ 195; Ex parte Fleischmann, 157 USPQ 155. The prior art cannot be combined as if appellant’s invention was included therein as a part of the knowledge possessed by one of ordinary skill in the art. In combining references, the prior art references

themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

It is clear that the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or "template" to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on §103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner's conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in prior art which is not concerned with the problem sought to be solved by the claimed invention, this ground of rejection is not sustainable.

It should be readily apparent that the Examiner has not made out a *prima facie* case of obviousness based on any combination of teachings of JP and Heaton. Accordingly, a reversal of this ground of rejection is respectfully requested.

Even if it should be concluded that any *prima facie* case of obviousness has been made out, such has been previously rebutted. Thus, the Heaton article reports that 40% of the subjects tested with the disclosed formulation complained of headache. This portion of the disclosure contraindicates the safety and efficacy of the reference composition, thereby teaching against the claimed invention.

CONCLUSION

It is respectfully requested that the final rejection of record be reversed and the application remanded to the Examiner for immediate allowance.

Respectfully submitted,

MILES & STOCKBRIDGE

A handwritten signature in black ink, appearing to read 'Dennis P. Clarke', is written over the firm name.

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APPENDIX

Claims on Appeal (Claims 24-29)

24. A composition for the treatment of erectile dysfunction in human males, the composition comprising a mixture of effective amounts of glyceryl trinitrate and lanolin and also containing water.

25. A cosmetic product comprising the composition of claim a mixture of effective amounts of glyceryl trinitrate and lanolin and also containing water.

26. A composition or product according to claim 24 or 25 wherein said glyceryl trinitrate is adsorbed on a solid stabilizer in finely-divided particulate form.

27. The composition or product of claim 26 wherein said glyceryl trinitrate is adsorbed on lactose at a concentration of from 5 to 20% by weight.

28. The composition or product of claim 26 wherein said glyceryl trinitrate is present in a concentration of up to 5% by weight.

29. The composition or product of claim 26 consisting essentially of 10 wt% glyceryl trinitrate (10% in lactose), 44 wt % lanolin, 21 wt% white soft paraffin B.P. and 25 wt% demineralized water.